Company name:
Contact name:
Contact email:
Company web site: ☐ Include on posting

Grant number associated with success story:

Describe your success story below. This could include: obtaining regulatory clearance/ approval, achieving a sales or marketing milestone, completing a clinical trial phase, receiving outside investment, entering into a strategic alliance or partnership, executing an IPO, or any other achievement leading toward the commercialization of a product or service funded through the NHLBI SBIR/STTR program. Only this narrative, your company name, and web site (optional) will be posted if your success story is chosen. Please use 5000 characters or less. If you would like to submit a press release or other documentation, you can email it to nhlbi_sbir@nhlbi.nih.gov with the subject "Success story for grant number xxxxxxxx" after submitting this form. **Pressing the "Submit Success Story" will launch your email program. You must send the email to complete the submission process.**

Please answer the following questions. The answers are for internal NIH use only to help us evaluate and improve the SBIR/STTR program.

1. List patents (U.S. and international), copyrights, trademarks, and invention reports, if any, that resulted from the award.

	# Filed (Enter Numeric Value)	# Approved (Enter Numeric Value)	Patent Numbers (separated by commas)
Patents			
Copyrights			
Trademarks			
Invention Reports			

Describe other printed materials or demonstration of IP protection, if any, that resulted from the award. (Please use 500 characters or less)

2. Check the boxes that best describe the technology developed from this SBIR/STTR.
(Check all that apply)

☐ **Small Molecules**: Involves the development or reformulation of drugs as chemical substances used in the treatment, cure, prevention, or diagnosis (*in vivo*, imaging agents, etc) of disease or used to otherwise enhance physical or mental well-being; includes so-called “naturopathic” or naturally-derived substances in alternative care regimes.

☐ **Biologics:** Involves a medicinal product created by biologic processes, such as a vaccine, blood or blood component, allergenic, somatic cell, gene therapy, tissue, recombinant therapeutic protein, or living cells.

☐ **Companion Product:** Involves a diagnostic, therapeutic, or device that must be used in combination with another diagnostic, therapeutic, or device type (e.g. companion diagnostic for a specific therapy; a small molecule that activates expression from a gene therapy vector; a device and imaging agent that work together). This does not include "drug cocktails." The Phase II project may include only one aspect of the companion product.

☐ **Medical Devices**: Involves the development and/or use of instruments or machines, used in the diagnosis of disease or in the cure, mitigation, treatment, or prevention of disease or conditions associated with the deterioration of physiological function (for e.g., prostheses); this would also include medical imaging devices and the use of innovative materials to construct new devices.

☐ **Research Tools**: Involves the development of new or improved tools, devices, and sensors to enhance laboratory or field studies on humans, animals, or any model system. This includes tools to broaden the research knowledge base and for biomonitoring.

☐ **Biotechnology**: Involves the use of microorganisms, such as bacteria or yeasts, to perform specific industrial or manufacturing processes.

☐ ***In Vitro and Ex Vivo* Diagnostics**: Involves the use of tools (software, hardware or combinations) to identify or screen for research purposes and for the nature of medical conditions, determining whether specified diseases or disease processes are present in living organisms. Includes the use of these tools for non-clinical screenings and to provide insights in the work of clinicians, providers, manufacturers of equipment, and companies involved in therapies associated with disease.

☐ **Healthcare IT**: Involves approaches and tools derived from information technology that allow for the management of research, educational and medical information. Includes software, media and educational tools and digital health.

☐ **Other**, please specify

Describe the technology's intended commercial application, potential market size, and who will use it. (Please use 500 characters or less)

3. Check the box that best describes the current R&D status of the product.

☐ Non-clinical technology in prototype development/testing stage
☐ Non-clinical technology in full development/testing stage
☐ Pre-clinical development
☐ Clinical development
☐ Commercially available
☐ Discontinued
☐ Other (describe below)

Describe the current status of this product and explain reasons if discontinued. (Please use 500 characters or less)

4. Check the boxes that best describe the regulatory approval status for your product, process, or service.
(Check all that apply)

☐ Not applicable (no regulatory approval needed)

FDA approval:

PMA	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
510(k)	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
IDE	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
BLA	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
IND	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
NDA	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected

FDA Facility Registrations ☐ Not yet submitted ☐ Submitted ☐ Approved ☐ Rejected

EU/UK approval:
CE Mark ☐ Not yet submitted ☐ Submitted ☐ Approved ☐ Rejected

☐ Other regulatory submissions and approvals (Please use 500 characters or less to list all other planned and submitted regulatory applications and include any foreign submissions):

5. Check the boxes that best describe the reimbursement approval status of your product, process, or service.
(Check all that apply)

☐ Not applicable

CMS Reimbursement ☐ Not yet submitted ☐ Submitted ☐ Approved ☐ Rejected
Private Payer Reimbursement ☐ Not yet submitted ☐ Submitted ☐ Approved ☐ Rejected

6. Check the boxes that best describe the status of clinical trials for your product, process, or service.
(Check all that apply)

☐ Not applicable

Phase I clinical trial	☐ Ongoing	☐ Completed
Phase II clinical trial	☐ Ongoing	☐ Completed
Phase III clinical trial	☐ Ongoing	☐ Completed
Premarket approval (PMA) device trial	☐ Ongoing	☐ Completed
Phase IV Postmarketing study	☐ Ongoing	☐ Completed
Outside of the United States (OUS)	☐ Ongoing	☐ Completed

7. Describe company outcomes occurring, at least in part, as a result of this award.
(Check all that apply)

☐ Follow on funding Total cumulative dollar amount
(check all that apply and enter amount invested)
☐ Venture Capital (VC) Total cumulative dollar amount

☐ Angel Total cumulative dollar amount
☐ State/Local Total cumulative dollar amount
☐ Strategic partnership Total cumulative dollar amount
☐ Federal Total cumulative dollar amount
☐ Internal SBC Funds Total cumulative dollar amount
☐ Other (Foundations, bank loans, etc) Total cumulative dollar amount

☐ Out-licensing agreements/sale of IP Number
Total cumulative dollar amount
Nature of agreement

☐ In-licensing agreements
Number
Total cumulative dollar amount
Nature of agreement

☐ Strategic partnership(s) which do not include funding
Name(s)

☐ Spin-off companies
Name(s)
☐ Public offering
Country
Year
Value
☐ Merger or acquisition of Awardee
Name of acquirer
Year
Total value

Further description of any economic, commercial or other outcomes attributable to the award, including any pending investments or strategic partnerships. List names and nature of significant partnerships, if available. (Please use 500 characters or less):

8. Describe the sales or revenues, if any, which resulted from this SBIR/STTR award (not including award funds).

☐ No sales or revenue to date.
Please provide projected date of first sale/commercial service launch (MM/DD/YYYY):

Sales or service to:
(check all that apply and enter the total cumulative dollar amount to date)
☐ Federal
☐ Private sector
☐ Other

List the generic and/or commercial name of the product(s), process(es), or service(s), if any, that resulted, at least in part, from this award. If applicable, indicate the number of products sold.
** If the SBIR/STTR-supported product is a component of a larger commercial product, please list the sales revenues of both the component and the commercial product*

Product or Service	Revenues Generated	Number Sold (if applicable)

9. Provide the current number of employees at company (total full time equivalents [FTEs]):
Provide an estimate of the total number of FTEs at company attributable to all previous and current SBIR/STTR funding received:
Provide the number of FTEs (including company and sub-contractors) directly supported by this award:

Submit Success Story

If the submit button does not work, you can save this form and email it to nhlbi_sbir@mail.nih.gov with the subject line "Success Story."